



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maheswaran *et al.*

Appl. No.: 10/646,784

Filed: August 25, 2003

**For: Use of Mullerian Inhibiting  
Substance and Interferon for  
Treating Tumors**

Confirmation No. 1100

Art Unit: 1614

Examiner: *To Be Assigned*

Atty. Docket: 0609.5130001/LBB/FRC

**Information Disclosure Statement under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97, and 1.98. Copies of documents AA1-AK1, AA2-AK2, AA3-AK3, and AA4-AB4 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "the Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." Copies of all other cited documents are provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be

prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

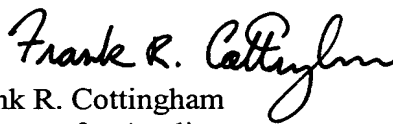
This Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

Date: June 16, 2004

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.5130001/LBB/FRC

APPLICATION NO.  
10/646,784

APPLICANT  
Maheswaran et al.

FILING DATE  
August 25, 2003

GROUP  
1614

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE
	AA1	4,404,188	09/13/1983	Donahoe et al.	07/29/1981
	AB1	4,487,833	12/11/1984	Donahoe et al.	03/01/1982
	AC1	4,753,794	06/28/1988	Donahoe	06/24/1986
	AD1	4,897,355	01/30/1990	Eppstein et al.	10/29/1987
	AE1	4,946,787	08/07/1990	Eppstein et al.	10/27/1989
	AF1	5,010,055	04/23/1991	Donahoe	U.S. Filed: 04/25/1988 102(e) Date: 04/25/1988
	AG1	5,011,687	04/30/1991	Donahoe et al.	10/29/1985
	AH1	5,047,336	09/10/1991	Cate et al.	10/30/1985
	AI1	5,049,386	09/17/1991	Eppstein et al.	05/15/1990
	AJ1	5,110,904	05/05/1992	Haviv et al.	07/10/1990
	AK1	5,139,941	08/18/1992	Muzyczka et al.	10/25/1991

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 89/06695 A1 /	07/27/1989	WIPO			Yes No
	AM1	WO 90/11092 A1 /	10/04/1990	WIPO			Yes No
	AN1	WO 94/12650 A1 /	06/09/1994	WIPO			Yes No
	AO1	WO 94/29469 A1 /	12/22/1994	WIPO			Yes No
	AP1	WO 95/16709 A2 /	06/22/1995	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>1</u>	Alam, J., et al., "Comparative Pharmacokinetics and Pharmacodynamics of Two Recombinant Human Interferon Beta-1a (IFN $\beta$ -1a) Products Administered Intramuscularly in Healthy Male and Female Volunteers," <i>Pharm. Res.</i> 14:546-549, Plenum Press (1997) ✓
AS	<u>1</u>	Anderson, W.F., "Prospects for Human Gene Therapy," <i>Science</i> 226:401-409, American Association for the Advancement of Science (1984) ✓
AT	<u>1</u>	Attisano, L. and Lee-Hoeflich, S.T., "The Smads," <i>Genome Biol.</i> 2:3010.1-3010.8, BioMed Central Ltd. (August 2001) ✓

EXAMINER

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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE
	AA2	5,173,414	12/22/1992	Lebkowski et al.	10/30/1990
	AB2	5,198,420	03/30/1993	Donahoe et al.	06/30/1992
	AC2	5,310,880	05/10/1994	Donahoe et al.	04/12/1991
	AD2	5,354,678	10/11/1994	Lebkowski et al.	12/21/1992
	AE2	5,359,033	10/25/1994	Cate et al.	U.S. Filed: 06/23/1993 102(e) Date: 07/23/1990
	AF2	5,427,780	06/27/1995	Cate et al.	10/05/1992
	AG2	5,436,146	07/25/1995	Shenk et al.	01/21/1993
	AH2	5,459,127	10/17/1995	Felgner et al.	09/16/1993
	AI2	5,474,935	12/12/1995	Chatterjee et al.	07/25/1994
	AJ2	5,478,745	12/26/1995	Samulski et al.	12/04/1992
	AK2	5,484,768	01/16/1996	Donahoe et al.	U.S. Filed: 03/08/1993 102(e) Date: 03/08/1993

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 96/29411 A1 /	09/26/1996	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Baarends, W.M., et al., "A novel member of the transmembrane serine/threonine kinase receptor family is specifically expressed in the gonads and in mesenchymal cells adjacent to the müllerin duct," <i>Development</i> 120:189-197, The Company of Biologists Ltd. (1994) /
	AS	2	Baichwal, V.R. and Baeuerle, P.A., "Apoptosis: Activate NF-κB or die?" <i>Curr. Biol.</i> 7:R94-R96, Current Biology (1997) /
	AT	2	Baker, M.L. and Hutson, J.M., "Serum Levels of Mullerian Inhibiting Substance in Boys throughout Puberty and in the First Two Years of Life," <i>J. Clin. Endocrinol. Metab.</i> 76:245-247, The Endocrine Society (1993) /

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE
	AA3	5,538,892	07/23/1996	Donahoe et al.	11/04/1993
	AB3	5,547,854	08/20/1996	Donahoe et al.	10/04/1994
	AC3	5,589,377	12/31/1996	Lebkowski et al.	06/06/1995
	AD3	5,580,859	12/03/1996	Felgner et al.	03/18/1994
	AE3	5,589,466	12/31/1996	Felgner et al.	01/26/1995
	AF3	5,661,126	08/26/1997	Donahoe et al.	07/07/1994
	AG3	5,593,972	01/14/1997	Weiner et al.	09/21/1993
	AH3	5,652,224	07/29/1997	Wilson et al.	02/24/1995
	AI3	5,676,954	10/14/1997	Brigham	05/08/1995
	AJ3	5,693,622	12/02/1997	Wolff et al.	06/07/1995
	AK3	5,703,055	12/30/1997	Felgner et al.	01/26/1994

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Bardin, C.W., et al., "Chapter 25. Androgens," in: <i>Reproductive Endocrinology, Surgery, and Technology</i> , Adashi, E.Y., et al., eds., Lippincott-Raven Publishers, Philadelphia, PA, pp. 505-525 (1995) ✓
	AS	3	Barkett, M. and Gilmore, T.D., "Control of apoptosis by Rel/NF-κB transcription factors," <i>Oncogene</i> 18:6910-6924, Stockton Press (1999) ✓
	AT	3	Baron, S., et al., "The Interferons. Mechanisms of Action and Clinical Applications," <i>J. Am. Med. Assoc.</i> 266:1375-1383, American Medical Association (1991) ✓

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U.S. PATENT DOCUMENTS					
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	AA4	5,906,979	05/25/1999	Allan	01/27/1998
	AB4	5,912,224	06/15/1999	Donahoe et al.	02/21/1997
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FOREIGN PATENT DOCUMENTS							
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>4</u>	Baron, S. and Dianzani, F., "The interferons: a biological system with therapeutic potential in viral infections," <i>Antiviral Res.</i> 24:97-110, Elsevier Science B.V. (1994) ✓
	AS	<u>4</u>	Barrie, S.E., et al., "Biochemistry and Pharmacokinetics of Potent Non-steroidal Cytochrome P450 <sub>17α</sub> Inhibitors," <i>J. Steroid Biochem. Molec. Biol.</i> 60:347-351, Elsevier Science Ltd. (1997) ✓
	AT	<u>4</u>	Behringer, R.R., et al., "Abnormal sexual development in transgenic mice chronically expressing Müllerian inhibiting substance," <i>Nature</i> 345:167-170, Macmillan Publishers (1990) ✓

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>5</u>	Behringer, R.R., et al., "Müllerian-Inhibiting Substance Function during Mammalian Sexual Development," Cell 79:415-425, Cell Press (1994)✓
	AS	<u>5</u>	Belldgrun, A., et al., "Human renal Carcinoma Line Transfected With Interleukin-2 and/or Interferon $\alpha$ Gene(s): Implications for Live Cancer Vaccines," J. Natl. Cancer Inst. 85:207-216, Oxford University Press (1993)✓
	AT	<u>5</u>	Bissonnette, R.P., et al., "Apoptotic cell death induced by c-myc is inhibited by bcl-2," Nature 359:552-554, Nature Publishing Company (1992)✓

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Borelli, E., et al., "Targeting of an inducible toxic phenotype in animal cells," <i>Proc. Natl. Acad. Sci. USA</i> 85:7572-7576, National Academy of Sciences (1988) ✓
	AS	<u>6</u>	Brown, K., et al., "Control of I $\kappa$ B- $\alpha$ Proteolysis by Site-Specific, Signal-Induced Phosphorylation," <i>Science</i> 267:1485-1488, American Association for the Advancement of Science (1995) ✓
	AT	<u>6</u>	Cate, R.L., et al., "Isolation of the Bovine and Human Genes for Müllerian Inhibiting Substance and Expression of the Human Gene in Animal Cells," <i>Cell</i> 45:685-698, Cell Press (1986) ✓

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>7</u>	Cate, R.L., et al., "Development of Mullerian Inhibiting Substance as an Anti-cancer Drug," <i>Cold Spring Harbor Symposia Quant. Biol.</i> LI:641-647, Cold Spring Harbor Laboratory (1986) ✓
	AS	<u>7</u>	Cate, R.L., et al., "Mullerian Inhibiting Substance: A Fetal Growth Inhibitor with Homology to TGF- $\beta$ ," <i>J. Cell. Biochem. Supplement</i> 12A:183, Abstract No. D005, Alan R. Liss (1988) ✓
	AT	<u>7</u>	Chapman, R.S., et al., "A novel role for IRF-1 as a suppressor of apoptosis," <i>Oncogene</i> 19:6386-6391, Nature Publishing Group (2000) ✓

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Chen, C.-J., et al., "Role of Interferon Regulatory Factor-1 in the Induction of Biliary Glycoprotein (Cell CAM-1) by Interferon- $\gamma$ ," <i>J. Biol. Chem.</i> 271:28181-28188, The American Society for Biochemistry and Molecular Biology, Inc. (1996) ✓
	AS	8	Chin, T., et al., "Human Müllerian Inhibiting Substance Inhibits Tumor Growth in Vitro and in Vivo," <i>Cancer Res.</i> 51:2101-2106, American Association for Cancer Research (1991) ✓
	AT	8	Clarke, T.R., et al., "Müllerian Inhibiting Substance Signaling Uses a Bone Morphogenetic Protein (BMP)-Like Pathway Mediated by ALK2 and Induces Smad6 Expression," <i>Mol. Endocrinol.</i> 15:946-959, The Endocrine Society (June 2001) ✓

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Clarkson, R.W.E., et al., "NF- $\kappa$ B Inhibits Apoptosis in Murine Mammary-Epithelia," <i>J. Biol. Chem.</i> 275:12737-12742, The American Society for Biochemistry and Molecular Biology, Inc. (2000) ✓
	AS	<u>9</u>	Clumeck, N. and Hermans, P., "Antiviral Drugs Other than Zidovudine and Immunomodulating Therapies in Human Immunodeficiency Virus Infection," <i>Am. J. Med.</i> 85:165-172, Excerpta Medica (1988) ✓
	AT	<u>2</u>	Colamonici, O.R., et al., "Multichain Structure of the IFN- $\alpha$ Receptor on Hematopoietic Cells," <i>J. Immunol.</i> 148:2126-2132, The American Association of Immunologists (1992) ✓

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>10</u>	Colamonic, O.R. and Domanski, P., "Identification of a Novel Subunit of the Type I Interferon Receptor Localized to Human Chromosome 21," <i>J. Biol. Chem.</i> 268:10895-10899, The American Society for Biochemistry and Molecular Biology, Inc. (1993)
	AS	<u>10</u>	Cornetta, K. and Anderson, W.F., "Protamine sulfate as an effective alternative to polybrene in retroviral-mediated gene-transfer: implications for human therapy," <i>J. Virolog. Meth.</i> 23:187-194, Elsevier Science Publishers B.V. (1989)
	AT	<u>10</u>	Crowley, W.F., Jr., "Neuroendocrine & Gonadal Control of Male Reproduction," application for National Institute of Child Health and Human Development, grant no. 2 U54 HD-28138-10 (April 1, 2000 or later)✓

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>11</u>	Culver, K.W., et al., "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors," <i>Science</i> 256:1550-1552, American Association for the Advancement of Science (1992) ✓
	AS	<u>11</u>	Culver, K., et al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man," <i>Proc. Natl. Acad. Sci. USA</i> 88:3155-3159, National Academy of Sciences (1991) ✓
	AT	<u>11</u>	Deamer, D. and Bangham, A.D., "Large Volume Liposomes by an Ether Vaporization Method," <i>Biochim. Biophys. Acta</i> 443:629-634, Elsevier Scientific Publishing Co. (1976) ✓

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>12</u>	Debs, R.J., et al., "Regulation of Gene Expression in Vivo by Liposome-mediated Delivery of a Purified Transcription Factor," <i>J. Biol. Chem.</i> 265:10189-10192, The American Society for Biochemistry and Molecular Biology (1990) ✓
	AS	<u>12</u>	di Clemente, N., et al., "Cloning, Expression, and Alternative Splicing of the Receptor for Anti-Müllerian Hormone," <i>Mol. Endocrinol.</i> 8:1006-1020, The Endocrine Society (1994) ✓
	AT	<u>12</u>	Doherty, G.M., et al., "Interferon Regulatory Factor Expression in Human Breast Cancer," <i>Ann. Surg.</i> 233:623-629, Lippincott, Williams & Wilkins, Inc. (May 2001) ✓

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>				ATTY. DOCKET NO. 0609.5130001/LBB/FRC		APPLICATION NO. 10/646,784	
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>13</u>	Domanski, P., et al., "Cloning and Expression of a Long Form of the $\beta$ Subunit of the Interferon $\alpha\beta$ Receptor That is Required for Signaling," <i>J. Biol. Chem.</i> 270:21606-21611, American Society for Biochemistry and Molecular Biology (1995) ✓
	AS	<u>13</u>	Donahoe, P.K., et al., "A Graded Organ Culture Assay for the Detection of Mullerian Inhibiting Substance," <i>J. Surg. Res.</i> 23:141-148, Academic Press, Inc. (1977) ✓
	AT	<u>13</u>	Donahoe, P.K., et al., "Mullerian Inhibiting Substance Inhibits Growth of a Human Ovarian Cancer in Nude Mice," <i>Ann. Surg.</i> 194:472-480, J.B. Lippincott Co. (1981) ✓

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>14</u>	Donahoe, P.K., "Mullerian Inhibiting Substance: A Tyrosine Kinase Inhibitor with Anticancer Effects," <i>J. Cell. Biochem., Supplement 12A:183</i> , Abstract No. D006, Alan R. Liss, Inc. (1988) ✓
	AS	<u>14</u>	Donahoe, P.K., "Müllerian Inhibiting Substance in Reproduction and Cancer," <i>Molec. Reprod. Develop. 32:168-172</i> , Wiley-Liss, Inc. (1992) ✓
	AT	<u>14</u>	Donahoe, P.K., "MIS Receptors-Novel Serine/Threonine Kinase Components," application for National Institute of Child Health and Human Development grant no. 2 R01 HD-32112-06A1 (January 15, 2000 or later) ✓

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	AR	<u>15</u>	Dron, M. and Tovey, M.G., "Interferon $\alpha/\beta$ Gene Structure and Regulation," in: <i>Interferon: Principles and Medical Applications</i> , Baron, S., et al., eds., The University of Texas Medical Branch at Galveston, Galveston, TX, pp. 33-45 (1992) ✓
	AS	<u>15</u>	Duncan, G.S., et al., "The Transcription Factor Interferon Regulatory Factor-1 Is Essential for Natural Killer Cell Function In Vivo," <i>J. Exp. Med.</i> 184:2043-2048, The Rockefeller University Press (1996) ✓
	AT	<u>15</u>	Engelhardt, J.F., et al., "Adenovirus-Mediated Transfer of the CFTR Gene to Lung of Nonhuman Primates: Biological Efficacy Study," <i>Human Gene Ther.</i> 4:759-769, Mary Ann Liebert, Inc. Publishers (1993) ✓

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	AR	<u>16</u>	Enoch, H.G. and Strittmatter, P., "Formation and properties of 1000-Å-diameter, single-bilayer phospholipid vesicles," <i>Proc. Natl. Acad. Sci. USA</i> 76:145-149, National Academy of Sciences (1979) ✓
	AS	<u>16</u>	Evan, G.I., et al., "Induction of Apoptosis in Fibroblasts by c-myc Protein," <i>Cell</i> 69:119-128, Cell Press (1992) ✓
	AT	<u>16</u>	Ezzeddine, Z.D., et al., "Selective Killing of Glioma Cells in Culture and in Vivo by Retrovirus Transfer of the Herpes Simplex Virus Thymidine Kinase Gene," <i>New Biol.</i> 3:608-614, W.B. Saunders (1991) ✓

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AR	<u>17</u>	Felgner, P.L., et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417, National Academy of Sciences (1987) ✓
AS	<u>17</u>	Ferrantini, M., et al., "IFN- $\alpha$ 1 Gene Expression into a Metastatic Murine Adenocarcinoma (TS/A) Results in CD8 <sup>+</sup> T Cell-Mediated Tumor Rejection and Development of Antitumor Immunity. Comparative Studies with IFN- $\gamma$ -Producing TS/A Cells," <i>J. Immunol.</i> 153:4604-4615, The American Association of Immunologists (1994) ✓
AT	<u>17</u>	Ferrantini, M., et al., " $\alpha$ 1-Interferon Gene Transfer into Metastatic Friend Leukemia Cells Abrogated Tumorigenicity in Immunocompetent Mice: Antitumor Therapy by Means of Interferon-producing Cells," <i>Cancer Res.</i> 53:1107-1112, American Association for Cancer Research (1993) ✓

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>18</u>	Fierlbeck, G., et al., "Pharmacodynamics of Recombinant IFN- $\beta$ During Long-Term Treatment of Malignant Melanoma," <i>J. Interferon Cytokine Res.</i> 16:777-781, Mary Ann Leibert, Inc. (1996) ✓
	AS	<u>18</u>	Fraley, R., et al., "Entrapment of a bacterial plasmid in phospholipid vesicles: Potential for gene transfer," <i>Proc. Natl. Acad. Sci. USA</i> 76:3348-3352, National Academy of Sciences (1979) ✓
	AT	<u>18</u>	Fraley, R., et al., "Introduction of Liposome-encapsulated SV40 DNA into Cells," <i>J. Biol. Chem.</i> 255:10431-10435, American Association for Biochemistry and Molecular Biology (1980) ✓

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	AR	<u>19</u>	Fuller, A.F., Jr., et al., "Mullerian Inhibiting Substance Reduction of Colony Growth of Human Gynecologic Cancers in a Stem Cell Assay," <i>Gynecol. Oncol.</i> 22:135-148, Academic Press, Inc. (1985) ✓
	AS	<u>19</u>	Fynn-Thompson, E., "Müllerian Inhibiting Substance Regulates Steroidogenesis in Rodent Leydig Tumor Cell Lines," Slides Presented at Harvard Medical School Prematriculation Summer Program Presentation, 13 pages (1998) ✓
	AT	<u>19</u>	Geymayer, S. and Doppler, W., "Activation of NF-κB p50/p65 is regulated in the developing mammary gland and inhibits STAT5-mediated β-casein gene expression," <i>FASEB J.</i> 14:1159-1170, The Federation of American Societies for Experimental Biology (2000) ✓

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>20</u>	Gouédard, L., et al., "Engagement of Bone Morphogenetic Protein Type IB Receptor and Smad1 Signaling by Anti-Müllerian Hormone and Its Type II Receptor," <i>J. Biol. Chem.</i> 275:27973-27978, The American Society for Biochemistry and Molecular Biology, Inc. (2000).✓
	AS	<u>20</u>	Green M., et al., "Analysis of human tonsil and cancer DNAs and RNAs for DNA sequences of group C (serotypes 1, 2, 5, and 6) human adenoviruses," <i>Proc. Natl. Acad. Sci. USA</i> 76:6606-6610, National Academy of Sciences (1979).✓
	AT	<u>20</u>	Gustafson, M.L., et al., Müllerian Inhibiting Substance as a Marker for Ovarian Sex-Cord Tumor," <i>New Engl. J. Med.</i> 326:466-471, Massachusetts Medical Society (1992) ✓

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>21</u>	Ha, T.U., et al., "Müllerian Inhibiting Substance Inhibits Ovarian Cell Growth through an Rb-independent Mechanism," <i>J. Biol. Chem.</i> 275:37101-37109, The American Society for Biochemistry and Molecular Biology, Inc. (2000) ✓
	AS	<u>21</u>	Hsieh, J.-T., et al., "Tumor Suppressive Role of an Androgen-regulated Epithelial Cell Adhesion Molecule (C-CAM) in Prostate Carcinoma Cell Revealed by Sense and Antisense Approaches," <i>Cancer Res.</i> 55:190-197, American Association for Cancer Research (1995) ✓
	AT	<u>21</u>	Hudson, P.L., et al., "An Immunoassay to Detect Human Mullerian Inhibiting Substance in Males and Females during Normal Development," <i>J. Clin. Endocrinol. Metabol.</i> 70:16-22, Williams and Wilkins (1990) ✓

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	AR	<u>22</u>	Hudson, P.L., et al., "Müllerian Inhibiting Substance (MIS) Slows the Cell Cycle Progression of Human Epidermoid Carcinoma, A431 Cells," <i>J. Cell Biol.</i> 115:276a, Abstract No. 1599, The Rockefeller University Press (1991)
	AS	<u>22</u>	Huang, J., et al., "Essential role of biliary glycoprotein (CD66a) in morphogenesis of the human mammary epithelial cell line MCF10F," <i>J. Cell Sci.</i> 112:4193-4205, The Company of Biologists Ltd. (1999)
	AT	<u>22</u>	Huang, J., et al., "Expression of Biliary Glycoprotein (CD66a) in Normal and Malignant Breast Epithelial Cells," <i>Anticancer Res.</i> 18:3203-3212, J.G. Delinassios (1998)

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	AR	<u>23</u>	Jacobs, J.L., "Immunologic Developments in AIDS - 1986," in: <i>The Year in Immunology</i> , Cruse, J.M., et al., eds., Karger, Basel, CH, pp. 303-309 (1988)
	AS	<u>23</u>	Josso, N., et al., "Anti-Müllerian Hormone: The Jost Factor," in: <i>Recent Progress in Hormone Research</i> , Bardin, C.W., ed., Academic Press, Inc., San Diego, CA, pp. 1-59 (1988)
	AT	<u>23</u>	Josso, N., et al., "Anti-Müllerian hormone in early human development," <i>Early Human Develop.</i> 33:91-99, Elsevier Scientific Publishers Ireland Ltd. (1993)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>24</u>	Jost, A., "Recherches Sur la Différenciation Sexuelle de L'Embryon de Lapin," in: <i>Archives D'Anatomie Microscopique et de Morphologie Expérimentale</i> , Avel, M., et al., eds., Masson & C <sup>ie</sup> , Paris, FR, pp. 18-315 (1946-1947)
	AS	<u>24</u>	Kaido, T., et al., "IFN- $\alpha_1$ Gene Transfection Completely Abolishes the Tumorigenicity of Murine B16 Melanoma Cells in Allogeneic DBA/2 Mice Decreases Their Tumorigenicity in Syngeneic C57BL/6 Mice," <i>Int. J. Cancer</i> 60:221-229, Wiley-Liss, Inc. (1995)
	AT	<u>24</u>	Kanamaru, C., et al., "Smad7 Is Induced by Norepinephrine and Protects Rat Hepatocytes from Activin A-induced Growth Inhibition," <i>J. Biol. Chem.</i> 276:45636-45641, The American Society for Biochemistry and Molecular Biology, Inc. (December 2001)

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	AR	<u>25</u>	Kaneda, Y., et al., "Increased Expression of DNA Cointroduced with Nuclear Protein in Adult Rat Liver," <i>Science</i> 343:375-378, American Association for the Advancement of Science (1989)
	AS	<u>25</u>	Kasid, A., et al., "Human gene transfer: Characterization of human tumor-infiltrating lymphocytes as vehicles for retroviral-mediated transfer in man," <i>Proc. Natl. Acad. Sci. USA</i> 87:473-477, National Academy of Sciences (1990)
	AT	<u>25</u>	Kendall, S.K., et al., "Targeted disruption of the pituitary glycoprotein hormone $\alpha$ -subunit produces hypogonadal and hypothyroid mice," <i>Genes &amp; Develop.</i> 9:2007-2019, Cold Spring Harbor Laboratory Press (1995)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>26</u>	Kim, J.H., et al., "The Inhibitory Effects of Müllerian-Inhibiting Substance on Epidermal Growth Factor Induced Proliferation and Progesterone Production of Human Granulosa-Luteal Cells," <i>J. Clin. Endocrinol. Metab.</i> 75:911-917, The Endocrine Society (1992)
	AS	<u>26</u>	Kirchhoff, S. and Hauser, H., "Cooperative activity between HER oncogenes and the tumor suppressor IRF-1 results in apoptosis," <i>Oncogene</i> 18:3725-3736, Nature Publishing Group (1999)
	AT	<u>26</u>	Kleinerman, D.I., et al., "Consistent Expression of an Epithelial Cell Adhesion Molecule (C-CAM) during Human Prostate Development and Loss of Expression in Prostate Cancer: Implication as a Tumor Suppressor," <i>Cancer Res.</i> 55:1215-1220, American Association for Cancer Research (1995)

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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.5130001/LBB/FRC	APPLICATION NO. 10/646,784
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	AR	<u>27</u>	Knazek, R.A., et al., "Culture of human tumor infiltrating lymphocytes in hollow fiber bioreactors," <i>J. Immunolog. Meth.</i> 127:29-37, Elviesier Science Publishers B.V. (1990)
	AS	<u>27</u>	Koller, B.H. and Smithies, O., "Inactivating the $\beta_2$ -microglobulin locus in mouse embryonic stem cells by homologous recombination," <i>Proc. Natl. Acad. Sci. USA</i> 86:8932-8935, National Academy of Sciences (1989)
	AT	<u>27</u>	Kowalik, T.F., et al., "E2F1 Overexpression in Quiescent Fibroblasts Leads to Induction of Cellular DNA Synthesis and Apoptosis," <i>J. Virol.</i> 69:2491-2500, American Society for Microbiology (1995)

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	AR	<u>28</u>	Kozarsky, K.F. and Wilson, J.M., "Gene therapy: adenovirus vectors," <i>Curr. Opin. Genet. Develop.</i> 3:499-503, Current Biology (1993)
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	AT	<u>28</u>	Kurian, M.S., et al., "Cleavage of Müllerian Inhibiting Substance Activates Antiproliferative Effects in Vivo," <i>Clin. Cancer Res.</i> 1:343-349, American Association for Cancer Research (1995)

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	AR	<u>29</u>	Lallemand, F., et al., "Smad7 inhibits the survival nuclear factor kB and potentiates apoptosis in epithelial cells," <i>Oncogene</i> 20:879-884, Nature Publishing group (February 2001)
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	AR	<u>30</u>	Lee, M.M., et al., "Müllerian-Inhibiting Substance Type II Receptor Expression and Function in Purified Rat Leydig Cells," <i>Endocrinol.</i> 140:2819-2827, The Endocrine Society (1999)
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>32</u>	MacLaughlin, D.T., et al., "Mullerian Duct Regression and Antiproliferative Bioactivities of Mullerian Inhibiting Substance Reside in its Carboxy-Terminal Domain," <i>Endocrinol.</i> 131:291-296, The Endocrine Society (1992)
	AS	<u>32</u>	Malone, R.W., et al., "Cationic liposome-mediated RNA transfection," <i>Proc. Natl. Acad. Sci. USA</i> 86:6077-6081, National Academy of Sciences (1989)
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	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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	AS	<u>33</u>	Miyazaki, M., et al., "Transforming Growth Factor- $\beta$ 1 Stimulates or Inhibits Cell Growth via Down- or Up-Regulation of p21/Waf1," <i>Biochem. Biophys. Res. Commun.</i> 246:873-880, Academic Press (1998)
	AT	<u>33</u>	Moolten, F.L. and Wells, J.M., "Curability of Tumors Bearing Herpes Thymidine Kinase Genes Transferred by Retroviral Vectors," <i>J. Natl. Cancer Inst.</i> 82:297-300, Oxford University Press (1990)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>34</u>	Moolten, F.L., "Tumor Chemosensitivity Conferred by Inserted Herpes Thymidine Kinase Genes: Paradigm for a Prospective Cancer Control Strategy," <i>Cancer Res.</i> 46:5276-5281, American Association for Cancer Research (1986)
	AS	<u>34</u>	Muzyczka, N., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <i>Curr. Topics Microbiol. Immunol.</i> 158:97-129, Springer-Verlag (1992)
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
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	AT	<u>35</u>	Novick, D., et al., "The Human Interferon $\alpha/\beta$ Receptor: Characterization and Molecular Cloning," <i>Cell</i> 77:391-400, Cell Press (1994)

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	AR	<u>36</u>	Nozawa, H., et al., "Loss of transcription factor IRF-1 affects tumor susceptibility in mice carrying the Ha-ras transgene or nullizygosity for p53," <i>Genes &amp; Develop.</i> 13:1240-1245, Cold Spring Harbor Laboratory Press (1999)
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	AR	<u>37</u>	Ogura, H., et al., "Implantation of Genetically Fibroblasts into Mice as Antitumor $\alpha$ -Interferon Therapy," <i>Cancer Res.</i> 50:5102-5106, American Association for Cancer Research (1990)
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	AR	<u>38</u>	Ostro, M.J., et al., "Incorporation of High Molecular Weight RNA into Large Artificial Lipid Vesicles," <i>Biochem. Biophys. Res. Commun.</i> 76:836-842, Academic Press, Inc. (1977)
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	AT	<u>39</u>	Pepinsky, R.B., et al., "Proteolytic Processing of Mullerian Inhibiting Substance Produces a Transforming Growth Factor- $\beta$ -like Fragment," <i>J. Biol. Chem.</i> 263:18961-18964, The American Society for Biochemistry and Molecular Biology, Inc. (1988)

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	AP						Yes No

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	AR	<u>40</u>	Percario, Z.A., et al., "Retinoic Acid is Able to Induce Interferon Regulatory factor 1 in Squamous Carcinoma Cells via a STAT-1 Independent Signalling Pathway," <i>Cell Growth Diff.</i> 10:263-270, American Association for Cancer Research (1999)
	AS	<u>40</u>	Pestka, S. and Langer, J.A., "Interferons and Their Actions," <i>Ann. Rev. Biochem.</i> 56:727-777, Annual reviews, Inc. (1987)
	AT	<u>40</u>	Pfister, K., et al., "Syncatalytic conformational changes in aspartame aminotransferase determined by hydrogen-deuterium exchange," <i>Proc. Natl. Acad. Sci. USA</i> 75:145-148, National Academy of Sciences (1978)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
0609.5130001/LBB/FRCAPPLICATION NO.  
10/646,784APPLICANT  
Maheswaran et al.FILING DATE  
August 25, 2003GROUP  
1614

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>41</u>	Picard, J.-Y., et al., "Cloning and expression of cDNA for anti-Müllerian hormone," <i>Proc. Natl. Acad. Sci. USA</i> 83:5464-5468, National Academy of Sciences (1986)
	AS	<u>41</u>	Platanias, L.C., et al., "Characterization of the $\alpha$ Subunit of the IFN- $\alpha$ Receptor," <i>J. Immunol.</i> 150:3382-3388, The American Association of Immunologists (1993)
	AT	<u>41</u>	Platanias, L.C., et al., "Tyrosine Phosphorylation of the $\alpha$ and $\beta$ Subunits of the Type I Interferon Receptor," <i>J. Biol. Chem.</i> 269:17761-17764, American Society for Biochemistry and Molecular Biology (1994)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>42</u>	Platanias, L.C., et al., "Differences in Interferon $\alpha$ and $\beta$ Signaling," <i>J. Biol. Chem.</i> 271:23630-23633, American Society for Biochemistry and Molecular Biology (1996)
	AS	<u>42</u>	Qureshi, S.A., et al., "Function of Stat2 Protein in Transcriptional Activation by Alpha Interferon," <i>Molec. Cell. Biol.</i> 16:288-293, American Society for Microbiology (1996)
	AT	<u>42</u>	Racine, C., et al., "Receptors for anti-Müllerian hormone on Leydig cells are responsible for its effects on steroidogenesis and cell differentiation," <i>Proc. Natl. Acad. Sci. USA</i> 95:594-599, National Academy of Sciences (1998)

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	AR	<u>43</u>	Ragin, R.C., et al., "Human Müllerian Inhibiting Substance: Enhanced Purification Imparts Biochemical Stability and restores Antiproliferative Effects," <i>Prot. Exp. Purif.</i> 3:236-245, Academic Press, Inc. (1992)
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	AT	<u>43</u>	Rey, R., et al., "Anti-Müllerian Hormone and Testosterone Serum Levels Are Inversely Related during Normal and Precocious Pubertal Development," <i>J. Clin. Endocrinol. Metab.</i> 77:1220-1226, The Endocrine Society (1993)

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	AN						Yes No
	AO						Yes No
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<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AR	<u>44</u>	Remington, J.P., ed., <i>Remington's Pharmaceutical Sciences</i> , Mack Publishing Company, Easton, PA, pp. 23-28 (1990)				
	AS	<u>44</u>	Romeo, G., et al., "IRF-1 as a Negative Regulator of Cell Proliferation," <i>J. Interferon Cytokine Res.</i> 22:39-47, Mary Ann Leibert, Inc. (January 2002)				
	AT	<u>44</u>	Rosenberg, M.B., et al., "Grafting Genetically Modified Cells to the Damaged Brain: Restorative Effects of NGF Expression," <i>Science</i> 242:1575-1578, American Association for the Advancement of Science (1988)				
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	AN						Yes No
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	AR	<u>45</u>	Rosenberg, S.A., et al., "Use of Tumor-Infiltrating Lymphocytes and Interleukin-2 in the Immunotherapy of Patients with Metastatic Melanoma," <i>New Engl. J. Med.</i> 319:1676-1680, Massachusetts Medical Society (1988)
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>46</u>	Rouiller-Fabre, V., et al., "Effect of Anti-Mullerian Hormone on Sertoli and Leydig Cell Functions in Fetal and Immature Rats," <i>Endocrinol.</i> 139:1213-1220, The Endocrine Society (1998)
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	AT	<u>46</u>	Salmon, P., et al., "Pharmacokinetics and Pharmacodynamics of Recombinant Human Interferon- $\beta$ in Healthy Male Volunteers," <i>J. Interferon Cyto. Res.</i> 16:759-764, Mary Ann Leibert, Inc. (1996)

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	AR	<u>47</u>	Santodonato, L., et al., "Local and systemic antitumor response after combined therapy of mouse metastatic tumors with tumor cells expressing IFN- $\alpha$ and HSVtk: perspectives for the generation of cancer vaccines," <i>Gene Ther.</i> 4:1246-1255, Stockton Press (1997)
	AS	<u>47</u>	Santodonato, L., et al., "Cure of Mice with Established Metastatic Friend Leukemia Cell Tumors by a Combined Therapy with Tumor Cells Expressing Both Interferon- $\alpha$ 1 and Herpes Simplex Thymidine Kinase Followed by Ganciclovir," <i>Human Gene Ther.</i> 7:1-10, Mary Ann Liebert, Inc. (1996)
	AT	<u>47</u>	Sarin, P.S., "Molecular Pharmacologic Approaches to the Treatment of AIDS," <i>Ann. Rev. Pharmacol.</i> 28:411-428, Annual Reviews, Inc. (1988)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>48</u>	Schaefer-Ridder, M., et al., "Liposomes as Gene Carriers: Efficient Transformation of Mouse L Cells by Thymidine Kinase Gene," <i>Science</i> 215:166-168, American Association for the Advancement of Science (1982)
	AS	<u>48</u>	Schiffer, M., et al., "Apoptosis in podocytes induced by TGF- $\beta$ and Smad7," <i>J. Clin. Invest.</i> 108:807-816, American Society for Clinical Investigation (September 2001)
	AT	<u>48</u>	Schutte, M., et al., "DPC4 Gene in Various Tumor Types," <i>Cancer Res.</i> 56:2527-2530, American Association for Cancer Research (1996)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>49</u>	Schwartz, A.R., et al., "Clinical Evaluation of Live, Oral Types 1, 2, and 5 Adenovirus Vaccines," <i>Am. Rev. Resp. Dis.</i> 109:233-238, American Lung Association (1974)
	AS	<u>49</u>	Segev, D.L., et al., "Müllerian Inhibiting Substance Inhibits Breast Cancer Cell Growth through an NFκB-mediated Pathway," <i>J. Biol. Chem.</i> 275:28371-28379, The American Society for Biochemistry and Molecular Biology, Inc. (2000)
	AT	<u>49</u>	Segev, D.L., et al., "Müllerian Inhibiting Substance Regulates NFκB Signaling and Growth of Mammary Epithelial Cells in Vivo," <i>J. Biol. Chem.</i> 276:26799-26806, The American Society for Biochemistry and Molecular Biology, Inc. (July 2001)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	50	Seifer, D.B., et al., "Gonadotropin-Releasing Hormone Agonist-Induced Differences in Granulosa Cell Cycle Kinetics Are Associated with Alterations in Follicular Fluid Mullerian-Inhibiting Substance and Androgen Content," <i>J. Clin. Endo. Metab.</i> 76:711-714, The Endocrine Society (1993)
	AS	50	Shah, P.C., et al., "Müllerian Inhibiting Substance as a Model for the Transforming Growth Factor- $\beta$ Family: Development of New Treatment Strategies," <i>Sem. Ped. Surg.</i> 5:182-190, W.B. Saunders Co. (1996)
	AT	50	Sharf, R., et al., "Functional Domain Analysis of Interferon Consensus Sequence Binding Protein (ICSBP) and Its Association with Interferon Regulatory Factors," <i>J. Biol. Chem.</i> 270:13063-13069, The American Society for Biochemistry and Molecular Biology, Inc. (1995)

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	AM						Yes No
	AN						Yes No
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	AR	<u>51</u>	Shaw, M.A., et al., "Aminoglutethimide and Ketoconazole: Historical Perspectives and Future Prospects," <i>J. Steroid Biochem.</i> 31:137-146, Pergamon Press (1988)
	AS	<u>51</u>	Sims, S.H., et al., "A Novel Interferon-Inducible Domain: Structural and Functional Analysis of the Human Interferon Regulatory Factor 1 Gene Promoter," <i>Molec. Cell. Biol.</i> 13:690-702, American Society for Microbiology (1993)
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	AR	<u>52</u>	Soule, H.D., et al., "Isolation and Characterization of a Spontaneously Immortalized Human Breast Epithelial Cell Line, MCF-10," <i>Cancer Res.</i> 50:6075-6086, American Association for Cancer Research (1990)
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	AR	<u>54</u>	Szoka, F., and Papahadjopoulos, D., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci. USA</i> 75:4194-4198, National Academy of Sciences (1978)				
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